

**Guidelines for**  
**PROGRAM PROJECT GRANTS**  
**National Institute of Biomedical Imaging and Bioengineering**  
**National Institutes of Health**  
**Department of Health and Human Services**

**CONTENTS**

Chapter 1:	Overview
I.	Introduction
II.	Pre-submission
III.	Characteristics of a Program Project
Chapter 2:	Guidelines for the Preparation of a Program Project Grant Application
I.	General Introduction
II.	Specific Instructions
Chapter 3:	Submission and Review of Applications
Institute Contacts	
Appendix	

## CHAPTER 1

### OVERVIEW

#### I. INTRODUCTION

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) Program Project Grant (P01) supports research in the broad areas of biomedical imaging and bioengineering, enabled by relevant areas of information science, physics, chemistry, mathematics, material science, engineering, computer sciences, and medical and life sciences. A P01 award is for the support of a broadly based multidisciplinary or multifaceted research program, which has a well-defined major objective or central theme. It is directed toward a range of scientific questions having a central research focus in contrast to the more narrow thrust of the traditional research project (R01). The program project involves the organized efforts of groups whose members are conducting research designed to elucidate the various aspects or components of the central theme. The leader of the overall P01 is called the principal investigator (PI); the leaders of the subprojects in a P01 are project leaders. A P01 requires a minimum of three research projects, which receive funding, led by three separate project leaders one of whom must be the PI. Each research project is usually under the leadership of a different experienced investigator and should contribute to the common theme of the total research effort. Collectively, these projects should demonstrate essential elements of unity and interdependence and result in a greater contribution to program goals than would occur if each subproject were pursued individually. It is expected that most of the collaborating scientists will be independent investigators. Thus, support of one senior investigator and several postdoctoral or research associate-level scientists as project leaders is not appropriate. The P01 grant is not intended to be a vehicle for departmental research support. In most cases, several departments should be represented.

The NIBIB accepts unsolicited P01 applications with the caveat that NIBIB permission is necessary for the acceptance of the application and for any budget that exceeds \$500,000 in direct costs in any year.

Individual subprojects of the P01 can be submitted as R01 applications. If a project submitted as an R01 application and as part of a P01 application receives independently derived priority scores/percentile rankings, which merit funding of both applications, funding of the P01 will take precedence over the R01, and the latter will be inactivated administratively.

In addition to the support of research projects, the P01 may provide funds for support of common resources and facilities (cores) that would be available for use by the individual projects comprising the program. Cores should furnish a group of investigators with some service, technique, determination, or instrumentation that will enhance the research endeavors, consolidate manpower effort, and contribute to cost effectiveness and quality. Core support may include personnel, equipment, supplies, services, and facilities required

for the integration of the projects toward their central research focus. A core must provide essential functions or services for at least two subprojects, which merit funding.

The size of a P01 is an important consideration. A P01 must have at least three approved subprojects. P01s that are too large may suffer from lack of communication and interaction among collaborators. On the other hand, smaller research endeavors may suffer from lack of a "critical mass" of investigators and would best be funded using the R01 mechanism.

## **II. PRE-SUBMISSION**

**Four to six months** prior to the submission of a new P01, the applicant is **encouraged** to meet with NIBIB staff (program and review; grants management, if requested by the PI) to discuss their planned application. This meeting is not necessary for revised applications or competing-continuation applications. In advance of that meeting, the applicant should send to NIBIB the NIH biographical sketches of the PI, the project leaders and core leaders, an estimated budget, a brief overview of the program (1 page or less), and a brief overview of the subprojects and cores (1 page or less for each subproject or core). Ideally this meeting would be in-person with the NIBIB staff. However, a teleconference is also possible. The purpose of the meeting is to engage in detailed discussions with the proposed PI and offer advice and suggestions. NIBIB staff, however, will not provide comments on the merit of the science proposed. Following this meeting, the PI should submit a revised description of the P01 including the same information as requested above.

**At least three months** prior to the submission of a new, renewal or revised P01, the PI should send a letter of intent. This letter should be sent to:

David T. George, Ph.D.  
Director, Office of Scientific Review  
Office of Science Administration  
National Institute of Biomedical Imaging and Bioengineering  
6707 Democracy Boulevard, Suite 920, MSC 5469  
Bethesda, MD 20892-5469 (20817 for FedEx, UPS, and other courier services)  
Phone: (301) 496-8633  
Fax: (301) 480-0675  
Email: GeorgeD@nih.gov

The letter of intent need include only:

1. Names of the principal investigator and the project leaders;
2. Descriptive title of the potential application;
3. Identification of the organization(s) involved; and
4. Announcement (if any) to which the application is responsive.

The purpose of the letter of intent is to establish communication between the potential applicant group and NIBIB staff. It is not part of the peer review material. Upon receipt of the letter, the appropriate NIBIB program director will contact the prospective PI to verify the scientific content of the application is within the mission of the NIBIB and to address any questions the PI may have. The NIBIB encourages pre-submission discussions of new P01 grant applications with staff to ensure that each application meets the policies and guidelines for P01 grants and to encourage more complete and well-prepared applications.

In addition, if the P01 budget requests \$500,000 or more in direct costs for any year, all applicants **must** contact NIBIB staff at least 6 weeks prior to any receipt date as per the NIH policy (<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>). In return, the applicant will receive written confirmation that NIBIB will accept the application for consideration for award. The letter of intent and letter requesting a budget in excess of \$500,000 can be sent in a single letter.

Applications submitted without prior consultation with staff, that are not prepared according to the NIBIB P01 guidelines, or do not meet the criteria for a P01 grant application will be returned to the applicant without review.

### **III. CHARACTERISTICS OF A PROGRAM PROJECT**

A P01 application should include:

- A. A clearly defined, unifying, central theme to which each component project relates and to which each research investigator contributes.
  - In keeping with the tradition of investigator-initiated research, the NIBIB expects the applicants to define the integrating theme and to develop multidisciplinary approaches used to accomplish the objectives of the proposed research.
  - The central theme should be clearly developed in the introduction with a rationale to indicate why the P01 is the appropriate mechanism to conduct the proposed multidisciplinary research.
  - The target goals anticipated on completion of the 5-year program should be outlined carefully in the introduction with special reference to contributions expected from the multidisciplinary team.
  - Examples of previous collaborations that may have led to the goals and proposed work of the program should be presented.
- B. Component research projects that contribute scientifically to the central theme of the program.
  - The relationship of the goals of each component project to the central theme should be described.

- Each component project requires a well-described plan for discovery or applied research, preliminary data, and a timetable for conducting the proposed investigations.
  - Subprojects may be technology development or hypothesis-driven basic or clinical research, or a combination of technology development and hypothesis-driven research. NIH defined clinical research is acceptable providing it is presented as one of several projects in the program and has objectives that can be completed in a 5-year project period. A P01 grant may not be used to support clinical trials. All research involving human subjects must conform to the NIH policies for inclusion of women, minorities, and children.
  - If core facilities are included, the technical/scientific and fiscal relationship of each component project to each core should be described.
  - A P01 requires a minimum of three submitted and funded component projects. Separate and independent project leaders should direct each project.
  - There is no requirement that the component projects be located at a single institution. However, it is incumbent upon the applicant to make clear how component projects and cores would function across institutions.
- C. A PI who is an established research scientist with the ability to ensure quality control and who has the experience to effectively administer and integrate all components of the program.
- The PI should devote to have a minimum of 25 percent effort to the grant.
  - A PI must be the project leader of one of the submitted and funded component projects. If the project submitted by the PI is judged by peer review to be of low scientific merit, this will markedly reduce the overall scientific merit ranking assigned to the entire application by the review committee.
  - The PI should be fully established at the applicant institution.
- D. Subproject leaders who provide expertise from several disciplines.
- Expertise will be evaluated on contributions to the scientific literature and potential to contribute to the overall theme of the P01. The P01 grant is not intended to be a vehicle for departmental research support. In most cases, several departments should be represented.
  - Project leaders should devote a minimum of 20 percent effort to each subproject for which they serve as project leader.
  - Investigators with excellent research training, though their total research experience is not yet optimal, may participate; however, it is expected that most of the project leaders will be investigators with significant research experience.
  - Project leaders should be fully established at their institution.
  - A P01 grant requires at least three independent project leaders, one of who will be the PI. At least three subprojects must be submitted and recommended for support for the P01 grant to be initiated.

- E. A plan to ensure close interaction among all participants so as to allow communication of ideas and results.
- The administrative structure should be organized to foster interactions among investigators and accelerate the pace of research. (See section B. above.)
  - Both internal and external advisory committees should be established to evaluate progress and the level of interaction among participants. In the P01 application, identify the expertise required on the External Advisory Committee. However, do not recruit or identify the members of the External Advisory Committee.
- F. A section titled "Synergy and Interactions Among Subprojects and Project Leaders." The section includes:
- Collaborative aspects of the research and the role of each subproject in the central theme of the application.
  - Multi-authored publications that demonstrate collaboration among investigators has taken place.
  - A description of inter-project utilization of resources and research findings.
  - A proposed schedule of seminar series, monthly group meetings, and semi-annual retreats.
  - Any other activities intended to promote close communication and collaboration.
  - The role of external and internal advisory committees, their interactions with each other and with the project leaders.

Applications must be complete at the time of submission, as neither site visits nor reverse site visits will be utilized in the review process.

## CHAPTER 2

### GUIDELINES FOR THE PREPARATION OF A PROGRAM PROJECT GRANT APPLICATION

This chapter supplements instructions in PHS Form 398 (<http://grants1.nih.gov/grants/funding/phs398/phs398.html>), but with sections modified and expanded to provide the additional information needed for the P01 application.

#### I. GENERAL INFORMATION

With the exceptions and additions noted below there are no major changes from the general requirements provided in the instructions for PHS Form 398. Page limitations specified for individual (R01) grant applications (25 pages) in PHS Form 398 apply to each subproject and core unit.

#### II. SPECIFIC INSTRUCTIONS

- A. Face Page (page 1 of application): Type "Program Project" on line 2. The title of the grant application must not exceed 56 characters. Complete all items on the face page of the application. This is page 1 of the application; number ALL succeeding pages accordingly.
- B. Description, Performance Sites and Key Personnel (see PHS Form 398 Instructions)
  - In the block requesting key personnel, add the position title, department, and institution for each individual.
- C. Table of Contents (**Figure 1**)
  - Prepare a detailed table of contents that will enable the readers to find specific information readily. List each subproject, the budget for each subproject, each core unit, and the budget for each core unit, and supply the page number for each item. Identify each subproject by title, assign each subproject a number that reflects the order in which the projects are presented in the application, and provide the name of the project leader. (In the case of competing continuation applications, identify each subproject with the same number as used in the previous application, or, if subprojects have been dropped or added, arrange the numbers in sequence and correlate the subproject being renewed with its former number.)
- D. Detailed Budget for Initial Budget Period (**Table 1**)

- i. For all P01 applications
  - A detailed budget will be required for EACH SUBPROJECT AND EACH CORE UNIT in their respective sections of the application. (See below under Research Plan)
  - To aid in the review of your application, it is suggested that you incorporate a detailed budget for all requested support during the first year (See Sample Table 1). For each category, such as "Personnel," "Equipment," "Supplies," "Travel," and "Other Expenses," give the amount requested for EACH SUBPROJECT AND CORE UNIT with subtotals. If contractual arrangements or "purchased services" involving other institutions or organizations are anticipated (as in subproject 5 in Sample Table 1), include total (direct and indirect) costs associated with such third party participation in the "Consortium/Contractual Costs." In addition, a complete budget for a consortium project is to be developed and identified as such.
- ii. New P01 Applications
  - New applications may request up to \$1.4 million direct costs, (not including indirect costs for collaborating institutions) in each year.
  - Equipment is included in this budget ceiling.
  - Requests for expensive items of equipment that cause an application to exceed these limits may be permitted on a case-by-case basis following staff consultation. However, applicants should make every attempt to include all equipment in the ceiling amount. They must discuss the equipment request with NIBIB early in the planning phase and must receive written permission from the Institute to include these costs in their budget request. All requests for such equipment that may cause the application to exceed the limits will require in-depth justification. Final decisions will depend on the nature of the justification and the Institute's fiscal situation.
- iii. Competing Continuation P01 Applications
  - Competing renewal applications may request up to \$1.4 million direct cost or a 10 percent increase over the recommended amount shown on the award statement for the last non-competing year, whichever is less (not including indirect costs for collaborating institutions and non-recurring costs, such as equipment).



- The same policy regarding equipment that is stated above under "New Applications" applies to competing renewals.
- No P01 application budget may exceed the maximum of \$1.4 million direct cost in any year.

E. Budgets for Entire Proposed Period of Support.

- Prepare a budget by category that provides totals for each year of requested support. Requests for any increases in succeeding years must be clearly stated and the changes in percent effort and funds justified in the individual project and core unit budgets.

F. Biographical Sketch (see PHS Form 398 Instructions)

G. Other Support (see PHS Form 398 Instructions)

- As indicated in the PHS 398 instructions, the description of other support should be included as part of the biographical sketch (Research Support) and should not exceed two pages.

H. Resources (see below under Research Plan)

I. Research Plan: **The following sections should precede the subprojects:**

i. Program Introduction and Statement of Objectives

- A P01 application should be viewed as a group of interrelated research subprojects, each of which is not only individually meritorious technically or scientifically but is also complementary to the other subprojects in the program and contributes to the central theme.
- The theme of the proposed P01 should be established in the first few sentences of the general introduction.
- Describe the rationale for the overall program. Explain the strategy for achieving the objectives of the overall program and how each subproject and core unit relates to that strategy.
- The general introduction of the overall program description is the appropriate place to indicate any prior collaborative arrangements between investigators in the group, to emphasize the events that have led to the current application, to predict the anticipated unique advantages that would be gained by the research being conducted within the proposed P01, to describe how the subprojects are synergistic and mutually reinforcing (a diagram may be appropriate), and to explain how the subprojects

collectively would enhance the stated objective of the proposed research.

ii. Institutional Environment and Resources

- Briefly describe the features of the institutional environment that are relevant to the effective implementation of the overall program. As appropriate, describe available resources such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographic distribution of space and personnel, and consolidated resources. The information requested here supplants the "Resources" page in the PHS Form 398 grant application, which is NOT to be used.

iii. Organizational and Administrative Structure of the P01

- CHAIN OF RESPONSIBILITY. Describe in detail, and by diagram if appropriate, the chain of responsibility for decision making and administration, beginning at the level of a principal investigator and including investigators responsible for the direction of the research projects and core units. Indicate where, in the chain of responsibility, advisory groups (internal and external consultants) would be used, and describe the function of these consultants in ensuring quality control in the research efforts.
- EXTERNAL AND INTERNAL ADVISORY BOARDS. Every P01 should have plans for both an external advisory board and an internal advisory board. The external advisory board should consist of two to five advisers committed to the evaluation of the program by written documentation. New P01 grant applications should not constitute their external advisory board prior to or during the review of their application as individuals either invited or named to this group would not be able to serve as peer reviewers of the application. The internal advisory board should consist of three to five members outside of the program but within the same institution (or within neighboring institutions) who are able to assist in ongoing reviews on a more regular basis.
- SPECIFIC MANAGERIAL RESPONSIBILITIES: Indicate who would be responsible for assisting the principal investigator with the day-to-day administrative details, program coordination, and the planning and evaluation of the program.
- RELATION OF THE P01 ORGANIZATION TO THE ADMINISTRATION OF THE APPLICANT INSTITUTION: Describe the relation between the proposed P01 and other existing research, academic, and administrative units of the applicant

institution such as schools, centers, institutions, departments, and central administration.

- **CONSORTIUM ARRANGEMENTS:** If a grant application includes activities that involve institutions other than the sponsoring organization, the program is considered a consortium effort. Such activities may be included in a P01 grant application, but it is imperative that a consortium application be prepared so that the programmatic, fiscal, and administrative considerations are explained fully. As stated under Chapter 1, B., there is no requirement that all component projects be located at a single institution. However, it is incumbent upon the applicant to make clear and demonstrate how component projects and cores would function across institutions. The published policy governing consortia is available in the business offices of institutions that are eligible to receive Federal grants-in-aid. Consult the latest published policy governing consortia before developing the application. If clarification of the policy is needed, contact the Director, Office of Grants Management, Office of Science Administration, NIBIB, at 301-451-4789. Principal Investigators of P01s should exercise great diligence in preserving the interactions of the participants and the integration of the consortium projects with those of the parent institution, because synergy and cohesiveness could be diminished when projects are located outside the parent institution.
- **DESIGNATION OF REPLACEMENT FOR PRINCIPAL INVESTIGATOR:** Describe the procedure for appointing a replacement for the Principal Investigator, should the need arise. The NIBIB must approve the replacement of the Principal Investigator.

iv. Summary Report of Progress

Competing continuation applications must include a progress report that highlights achievements under the P01 since the last competitive review. A progress report is required for each subproject and core unit in other sections of the application. This composite summary/progress report must include the following information:

- A brief summary of major accomplishments that can be attributed to the project grant and a brief explanation of how these accomplishments have contributed to furthering the stated objectives of the program.

- A list of all publications and *in press* and submitted (not "in preparation") manuscripts that have resulted from the P01 grant. It is expected that these publications will acknowledge NIBIB P01 funding.
- A list of changes, if any, in the professional staffing since the last competitive review.
- A list of subprojects and core units, in tabular form, that have been discontinued, modified, or completed since the last competitive review, identified by number and title, with a brief explanation of the actions taken.
- A list of subprojects and core units in the current program, with the amount of current funding for each and the requested funding for the first budget period of each subproject and core unit that would be continued in the P01. Identify each as a "new" or "continuing" component.

## J. Subprojects

### 1. General Guidance

- EACH SUBPROJECT SHOULD FOLLOW THE FORMAT OF THE PHS FORM 398 and provide supplementary information when necessary for each section as indicated below. Describe each subproject and each core unit in the same detail required for an individual research project grant application, so that the scientific merit can be judged on the basis of the written proposal. Keep in mind that experts who can judge, collectively, all areas represented in the application but who may not be cognizant, individually, with each area of research proposed, will review the application. Therefore, the description of a subproject should be concise yet explicit enough to enable experts in related areas to understand the main thrust of each subproject.
- The research plan for each subproject is limited to 25 pages. Additional information concerning collaboration and integration between projects and cores and the contribution of each component to the program's specific goals should be succinct and must be included within the 25 pages. Unnecessarily long, wordy, or confusing presentations are usually perceived as indicative of premature or poorly planned research. The bibliography is not counted toward the 25-page limitation per subproject. Applications exceeding the page limitation or using inappropriate fonts or margins will be returned without review. Measure the printed page for font compliance before submission.

- Full-sized glossy photographs such as electron micrographs or gels may be sent to the Scientific Review Administrator (SRA) for distribution to the reviewers provided a photocopy (which could be reduced in size from the glossy photograph) is included within the 25-page limit of sections a-d of the Research Plan. In addition, the applicant may submit a CD to demonstrate motion data provided an appropriate frame from the data is included as an image in sections a-d of the research plan. All other graphs, diagrams, tables, and charts must be included within the 25-page limit of sections a-d in the Research Plan. The appendix is not to be used to circumvent the page limitations in the Research Plan. The appendix will not be duplicated with the rest of the application. Do not send the appendix material with the original application. After receipt of the application, the SRA will instruct the applicant as to when and where to send extra materials.

## 2. Specific Guidance

- a) Title and number each subproject so that it can be readily distinguished from any other subproject in the program. An individual ABSTRACT should be prepared for each subproject in the P01 as would be required for an R01. The title must NOT exceed 56 typewriter characters/spaces. DO NOT provide a face page (i.e., PHS Form 398 face page) for subprojects. Provide the name and academic title of the project leader and each participating investigator.
- b) The budget for each subproject must be presented according to the instructions indicated for PHS Form 398. A detailed budget is required for the first year and a budget for the entire proposed period of support. Include detailed budget justifications for all years.
- c) Resources: Describe in detail the facilities to be used. This is to be accomplished as described under "Resources."
- d) Research Plan: State the overall objective of the proposed research and explain the relationship of the subprojects to the central theme of the P01, their inter-relationship, and their relationship to the core units in the program.
  - i) Specific Aims
    - List the specific aims of the research project for the total period of requested support. Indicate the general priority of each aim in the overall research plan.
  - ii) Background and Significance
    - Review the most significant previous work and describe the current status of research in this field: document with complete references.
    - Indicate the relevance of the research project to the theme of the P01. In addition, specify the overall biomedical significance of the work proposed.
  - iii) Preliminary Studies/Progress Report
    - Refer to PHS form 398 Instructions for Preliminary Studies.
    - See under Summary Report of Progress.
  - iv) Research Design and Methods

- Give details of the research plan, including the description of the experiments or other work proposed; present the methods and techniques to be used; note the limitations, if any, of the procedures proposed. In so far as possible, describe the technology development and/or experiments in the sequence in which they would be conducted. (A time line might be useful.)
  - Discuss the kinds of results expected from the procedures, and explain how results would be analyzed and interpreted.
  - Discuss the extent to which anticipated results would satisfy the original aims and how those results would be important for planning the next steps in the proposed work.
- v) Human Subjects (see PHS Form 398 Instructions)
- The NIH policies concerning research on human subjects will apply. PHS Form 398 should be followed for human subjects information.
  - The NIH policy is that applicants proposing clinical research in grants and cooperative agreements include minorities, women and children in study populations. If women or minorities or children are excluded or inadequately represented in clinical research a clear and compelling rationale should be provided.
  - NIH-defined clinical research is acceptable providing it is presented as one of several projects in the program and has objectives that can be completed in a 5-year project period. A P01 grant may not be used to support clinical trials.
  - The composition of the proposed study population must be described in terms of gender and racial/ethnic groups. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included on PHS Form 398 in Section 1, C. 9 A-D of the Research Plan AND summarized in Section 1, C. 9E, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.
  - If the required information is not contained within the application, the application will be returned without review.
- vi) Vertebrate Animals (see PHS Form 398 Instructions.)
- If animals are involved, indicate what kinds are to be used and whether nonhuman primates are to be used, listing the special justifications for their use, and indicate all details for the care, use, treatment, and dispatch of all animals.
- vii) Literature Cited
- Include a full and complete citation for each reference in the text. Titles of reference publications including names and initials of **ALL** authors should be included.
  - Consortium/Contractual Arrangements and/or Collaborative Arrangements (See PHS Form 398 Instructions)

- Describe the collaboration of investigators within the P01. Describe in detail any other collaborative arrangements anticipated, either within the applicant institution or between institutions.
  - Consultants (See PHS Form 398 Instructions)
- e) Appendix
- Appendix material should NOT be included as part of the grant application. The SRA will contact the PI after receipt of the application for instructions on submitting appendix material.

#### K. Format of a Core Unit

A core unit is defined as a resource for the P01 that provides centralized services to more than one of the subprojects.

- ii) Title of core unit
  - Title and assign a LETTER designation to each core so that it can be readily distinguished from any other core unit. Do NOT exceed 56 typewriter characters/spaces for its title.
- iii) Names and title of investigators
  - Provide the name and academic title of the core unit leader and each participating investigator.
- iv) Budget for core unit
  - Present the budget for each core unit according to the instructions indicated for Form 398. A detailed budget (direct costs only) is required for the first year and a budget for the entire proposed period of support. Include detailed budget justifications for all years. If a consortium is involved, include the indirect costs of the consortium as part of the overall direct costs.
- v) Resources
  - Describe in detail the facilities to be used by EACH core unit. This is to be accomplished by completing the "Resource" page included in the PHS Form 398 grant application packet.
- vi) Description of core unit
  - Describe the function of the core unit as a resource to the P01. This section must present clearly the facilities, techniques, and professional skills that the core unit would provide. As justification for the core unit, briefly indicate the specific research projects that would use the resources of the core unit. A core unit is principally designed as a service of a resource component; it would be unusual to include research in a core unit (a possible exception would be methodology development). Please contact the Institute staff if you require guidance on this issue.
- vii) Relation of core units to research projects
  - Include in tabular form information concerning the research projects that each core unit would serve and the proportion of the cost of the core unit associated with each research project involved (**Table 2**).

## CHAPTER 3

### SUBMISSION AND REVIEW OF APPLICATIONS

The NIBIB will accept all new, competing renewal, and revised program project applications **ONLY** on the two regular receipt dates: June 1, and October 1. Neither site visits nor reverse site visits will be held as part of the peer review.

**Note:** Receipt dates are the same for new, renewal, and revised program project grant applications.

#### *The Application Review Cycles by Application Receipt Date*

Receipt by the NIBIB	Merit Review	Review by National Advisory Council	Earliest Possible Start Date
<b>June 1</b>	Sept.-Oct.	January	April 1
<b>Oct. 1</b>	Jan.-Feb.	May	July 1

The NIBIB **encourages** pre-submission discussions of new P01 grant applications with staff to ensure that each application meets the policies and guidelines for P01 grant applications and to encourage more complete and well-prepared documents. P01 grant applicants must receive written consent from the NIBIB to submit an application. In addition, submission of any application requesting a budget of greater than \$500,000 in direct costs in any year must receive the consent of the NIBIB. This requirement is based on NIH policy (<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>).

### I. APPLICATION AND REVIEW PROCESS

The following phases will normally comprise the process of submission and review of a P01 application:

#### A. PRE-SUBMISSION

1. For all P01 applications (new, renewal and revised), investigators are encouraged to discuss their intent to submit the application with NIBIB staff well in advance (4-6 months) of the receipt date. Such discussion is **encouraged** for all new P01 grant applications.
2. To plan the review schedule, not less than 3 months before submission of the application, a letter of intent should be sent to:

David T. George, Ph.D.  
Director, Office of Scientific Review  
Office of Science Administration  
National Institute of Biomedical Imaging and Bioengineering



6707 Democracy Boulevard, Suite 920, MSC 5469  
Bethesda, MD 20892-5469 (20817 for FedEx, UPS, and other courier services)  
Voice: (301) 496-8633  
Fax: (301) 480-0675  
Email: [GeorgeD@nih.gov](mailto:GeorgeD@nih.gov)

The letter should contain the overall program title and that for each of their component projects, together with the names and the institutions of the PI, the project leaders and key personnel.

3. To enable the Institute staff to advise whether the application meets the scientific and programmatic requirements for a P01 and is prepared according to the technical guidelines, it is recommended that a draft application be sent to the appropriate Program Director early in its preparation. It is the policy of the NIBIB that all applications requesting greater than \$500,000 in direct costs in any year will not be accepted without written Institute approval.

4. Questions concerning budgets and/or grants policy should be addressed to the Director, Office of Grants management of the NIBIB.

#### B. SUBMISSION

1. At the same time that the original and three copies of the grant applications are submitted to the Center for Scientific Review, at:

Center for Scientific Review  
National Institutes of Health  
Suite 1040  
6701 Rockledge Drive MSC 7710  
Bethesda, MD 20892-7710

TWO ADDITIONAL COPIES OF THE GRANT APPLICATION ARE REQUESTED TO BE SUBMITTED TO NIBIB BY A SEPARATE MAILING to:

David T. George, Ph.D.  
Director, Office of Scientific Review  
Office of Science Administration  
National Institute of Biomedical Imaging and Bioengineering  
6707 Democracy Boulevard, Suite 920, MSC 5469  
Bethesda, MD 20892-5469 (20817 for FedEx, UPS, and other courier services)  
Voice: (301) 496-8633  
Fax: (301) 480-0675  
Email: [GeorgeD@nih.gov](mailto:GeorgeD@nih.gov)

2. A copy of the letter indicating the willingness of the NIBIB to accept the application and a copy of the letter indicating that NIBIB will accept the application with a budget in excess of \$500,000 in direct costs in any year should be included with any P01 grant application.

#### C. SCIENTIFIC REVIEW

1. New, competing renewal, and revised P01 applications will be reviewed by a Special Emphasis Panel (SEP) composed of scientific peers convened to review one or more P01 applications with similar content.
2. Following receipt of an application, a Scientific Review Administrator (SRA) will be assigned responsibility for review. The PI will be notified of the SRA's name and contact information.
3. For all reviews, the SRA will:
  - a. Receive the appendix and reprints.
  - b. Alert reviewers that there will not be a site visit or a reverse site visit.
  - c. Transmit questions from reviewers to the applicant in preparation for the review, if the SRA believes they are critical to the review.
  - d. Allow submission of relevant new data acquired since the submission of the application. The time frame and details of permissible additional material will be transmitted to the applicant.
4. In addition:
  - a. Each subproject will receive a priority score based on its intrinsic stand-alone merit. This scoring process will be comparable to that for a R01 grant application.
  - b. It is possible that one or more of the components will have excellent scientific merit but fit poorly, or not at all, within the P01. Subprojects that are unrelated to the theme of the P01 may be deleted from the P01 and thus would be omitted from consideration when assigning the final priority score to the overall P01. The deletion of a subproject will reflect negatively on the PI's leadership.
  - c. The SEP will provide written comments on the overall program, as well as the synergy of the subprojects. The importance and contribution of each subproject to the overall program will be described in each subproject's critique.
  - d. Each Core Unit will be rated as "Recommended" or "Not Recommended".
  - e. The SEP will vote an overall score for the P01 grant application.

#### D. COUNCIL REVIEW

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) will assess the recommendations of the SEP. They will take into account the scientific merit of the component projects,

the overall merit of the program, programmatic considerations relevant to each application, and the total recommended budget.

#### E. FUNDING

1. The NIBIB and NACBIB are committed to the P01 as an important support mechanism to accomplish various research goals and opportunities.
2. The NIH Plan for Managing the Costs of Biomedical Research has placed an increased emphasis on the total cost of an application as a factor in the funding decision. This will have an impact on P01 grant applications and other grant applications having a high total cost.
3. The priority scores given to the component projects will be used as only one key factor in making funding decisions of P01s components.
4. P01 grants must consist of a minimum of three fundable component projects directed by at least three separate, independent project leaders and the PI's project must be fundable.

#### F. POST-AWARD ISSUES

1. If a component project group leader moves to another institution, the project is not automatically allowed to continue under a consortia relationship with the new institution. Therefore, in such a situation, the principal investigator should plan to justify to NIBIB staff the continuation of the component project based on its role in the overall P01.
2. The P01 grant may normally not be transferred administratively to another institution. An application from the new institution must be submitted for competitive review as described in this chapter.
3. The NIBIB will *consider* reinstatement into a P01 any subproject initially deleted from the P01 by the NIBIB if **all** of the following conditions have been met.
  - a. The subproject has been submitted as an R01, but not in response to an RFA.
  - b. Reinstatement is requested by the PI of the P01 grant, the PI of the R01, and the applicant institution.
  - c. The P01 is in the first or second year of the project period.
  - d. The scientific objectives of the R01 remain consistent with the major theme of the P01.
  - e. The R01 funds requested and approved are the same as, or lower than, those submitted in the P01, including subproject and associated core costs so that the total P01 budget cap would not be exceeded.
  - f. The percentile is equal to or better than that used for the official pay line at the Council for the competing investigator-initiated grants.

If all of these conditions are met, the NIBIB will consider reinstatement of the subproject (and associated core costs) for funding for the same period of time that remains in the parent P01.

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# APPENDIX

## FIGURE 1

### Table of Contents

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	PAGE #
A. Face Page (398-AA)* .....	
B. Description, Performance Site(s) and Key Personnel (398-BB) .....	
C. Table of Contents .....	
D. Composite Budget .....	
1. Detailed Budget for first 12-month budget period (Table 1) .....	
2. Budget for entire proposed project period (398-EE) .....	
E. Biographical Sketches (398-FF) .....	
F. Current Other Support (398-GG) .....	
G. Overall Research Plan**	
Introduction to Revised Application .....	
Introduction to Supplemental Application .....	
1. Program introduction and statement of objectives .....	
2. Institutional environment and resources .....	
3. Organizational & administrative structure of Program Project .....	
4. Specific managerial responsibilities .....	
5. Designation of replacement for Program Director .....	
6. Relation of the Program Project organization and .....	
administration to the applicant institution	
7. Summary report of progress (Renewal Applications) .....	
a) major accomplishments .....	
b) list of consultants .....	
c) list of publications .....	
d) changes in professional staffing .....	
e) list of projects and cores (current and renewal) .....	
H. Research Projects	
Project #. Title of Project .....	
Project Director	
Budget .....	
I. Core Facilities	
Core #. Title of Core .....	
Project Director	
Budget .....	
Distribution of Core Unit Costs Per-Project Table) .....	
J. Checklist (398-II) .....	

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\* See PHS 398 Application Kit

\*\* For Continuation, Supplemental and Revised Applications See NIBIB  
Program Project Administrative Guidelines for additional instructions

**TABLE 1**  
**Detailed Budget for the First 12-Month Period**  
**Direct Costs only**

Principal Investigator/Program Director (Last, first, middle):							
DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY				FROM	THROUGH		
PERSONNEL (Applicant organization only)				DOLLAR AMOUNT REQUESTED (omit cents)			
NAME	ROLE ON PROJECT	TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Project 1					30,000	3,000	33,000
Project 2					20,000	2,000	22,000
Project 3					25,000	2,500	27,500
Project 4					15,000	1,500	16,500
Core Unit A					22,000	2,200	24,200
Core Unit B					10,000	1,000	11,000
SUBTOTALS					122,000	12,200	134,200
CONSULTANT COSTS							
Project 2 (\$1,000)							
Core Unit A (\$2,000)							3,000
EQUIPMENT (Itemize)							
Project 1 25,000							
Project 2 19,500							
Project 3 15,000							
Core Unit A 20,400							79,900
SUPPLIES (Itemize by category)							
Project 1 3,500							
Project 2 8,000							
Project 3 0							
Project 4 10,000							
Core Unit A 2,400							
Core Unit B 6,600							30,500
TRAVEL \$1,250 each for Projects 1-4							5,000
PATIENT CARE COSTS		INPATIENT					
		OUTPATIENT					
ALTERATIONS AND RENOVATIONS (Itemize by category)							
Core Unit A - Cold Room Installation							50,000
OTHER EXPENSES (Itemize by category)							
Project 1 (\$1,000)							
Project 2 (\$1,500)							
Project 3 (\$3,000) Core Unit A (\$1,500)							
Project 4 (\$2,500) Core Unit B (\$1,000)							10,500
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD							\$313,100
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS PROJECT 5					53,000
		INDIRECT COSTS PROJECT 5					17,000
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)							\$383,100
PHS 398 (Rev. 5/01)							

**TABLE 2****Relation of Core Units to Research Projects**

<b>Projects</b>	<b>Core Unit A</b>	<b>Core Unit B</b>
<b>Project 1</b>	\$ 0	\$ 6,900
<b>Project 2</b>	13,100	6,000
<b>Project 3</b>	14,500	10,000
<b>Project 4</b>	10,000	0
<b>Project 5</b>	20,000	0
<b>TOTAL</b>	\$57,600	\$22,900